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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket No. OST-98-4777]  
RIN 2105-AC74

Amendments to Opiate Threshold Levels

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

  

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**SUMMARY:** This final rule makes conforming changes to the Department's drug testing procedures to incorporate changes made by the Department of Health and Human Services (DHHS) in the threshold levels of opiates. It is essential for the Department's drug testing procedures to remain consistent with the DHHS Guidelines, as Congress provided in the Omnibus Transportation Employee Testing Act of 1991.

**EFFECTIVE DATE:** The final rule takes effect on December 1, 1998.

**FOR FURTHER INFORMATION CONTACT:** Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, Room 10424, (202-366-9306); 400 7th Street, SW., Washington, DC 20590 or Mary Bernstein, Director, Office of Drug and Alcohol Policy and Compliance, Room 5405, (202-366-3784); 400 7th Street, SW., Washington, DC 20590.

**SUPPLEMENTARY INFORMATION:** On September 30, 1997, the Department of Health and Human Services (DHHS) published the final amendments to its Mandatory Guidelines for Federal Workplace Testing Programs (DHHS Guidelines) and indicated that May 1, 1998 would be the effective date for implementing these amendments. The amendments raised the initial and confirmatory test opiate thresholds from 300 nanograms per milliliter (ng/ml) to 2000 ng/ml. The DHHS amendments also established a new requirement to test for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/ml confirmatory level, for specimens that have tested positive for morphine on the confirmatory

test at the 2000 ng/ml level.

DHHS made changes to the testing cutoff levels for opiates following a notice and opportunity for comment. DHHS received 22 comments, of which a majority favored their proposal. Under the previous standards, 87 percent of laboratory positive opiate specimens were verified as negative by medical review officers (MROs). DHHS anticipates that these amendments will eliminate the identification of most individuals legitimately taking prescriptions including morphine or codeine or who have ingested poppy seeds.

Subsequent to the publication of the final amendments, it became clear that manufacturers would not be able to provide a sufficient supply of the modified opiate test kits by the May 1, 1998 effective date. On February 4, 1998, DHHS sent a letter to all Federal agencies, HHS certified and applicant drug testing laboratories, and immunoassay kit manufacturers informing them that the effective date would be delayed 4 to 6 months beyond the May 1, 1998 effective date.

DHHS chose December 1, 1998 as the new effective date for implementing the new opiate testing cutoff levels. DHHS was satisfied that manufacturers of test kits can provide an adequate supply of the modified opiate test kits to the laboratories by the December 1, 1998 effective date and that the laboratories would be able to use these opiate test kits to conduct the initial and confirmatory tests at the revised testing levels for opiates.

It is essential for the Department's drug testing procedures to remain consistent with the DHHS Guidelines, as Congress provided in the Omnibus Transportation Employee Testing Act of 1991. Consistency is also necessary to avoid confusion in the testing process. For these reasons, the Department is making conforming changes to its drug testing procedures in 49 CFR Part 40.

### Regulatory Process Matters

The final rule is considered to be a nonsignificant rulemaking under the DOT Regulatory Policies and Procedures. It is also a nonsignificant rule for purposes of Executive Order 12886. The Department certifies, under the Regulatory Flexibility Act, that the final rule does not have a significant economic effect on a substantial number of small entities. The rule does not impose any costs or burdens on regulated entities, since it will result in fewer opiate positives having to be reviewed by medical review officers. The rule has also been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

## Issuance of Final Rule Without Opportunity for Notice and Comment

With respect to the amendments to 49 CFR Part 40 concerning opiate testing levels, the Department has determined that it would be impracticable, unnecessary, or contrary to the public interest to provide an opportunity for notice and comment under 5 U.S.C. 553(b). These amendments are conforming amendments making the Department's drug testing procedures consistent with those of DHHS, as is required under the Omnibus Transportation Employee Testing Act of 1991. Before publishing its amendments to the DHHS Guidelines, DHHS solicited, received, and responded to public comment on the identical provisions. Since there has already been an opportunity for public comment on the substance of the changes and consistency is necessary to avoid confusion in the testing process, the Secretary finds good cause under 5 U.S.C. 553(d)(3) for the final rule to be effective less than 30 days from the date of publication in the Federal Register.

## Paperwork Reduction Act

This rule contains no new information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

## Unfunded Mandates Reform Act of 1995

The Department has determined that the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply to this rulemaking.

## Office of the Secretary of Transportation

### List of Subjects in 49 CFR Part 40

Drug testing, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons set forth in the preamble, the Office of the Secretary amends 49 CFR Part 40 as follows:

## **PART 40--PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS**

1. The authority citation for Part 40 continues to read as follows:

Authority: 49 U.S.C. 102, 301, 322; 49 U.S.C. App. 1301 nt., app. 1434 nt., app. 2717., app. 1618a.

Sec. 40.29 [Amended]

2. In section 40.29(e)(1), the initial test level for opiates appearing in the table is amended by revising the value “300” to “2000” and deleting the footnote “\*” that had specified a 25 ng/ml testing level if the immunoassay test was specific for free morphine.

3. In section 40.29(f)(1), the confirmatory test level for morphine appearing in the table is amended by revising the value from “300” to “2000”.

4. In section 40.29(f)(1), the confirmatory test level for codeine appearing in the table is amended by revising the value from “300” to “2000”.

5. In section 40.29(f)(1), the table is amended by adding a new line under opiates to read as follows:

Sec. 40.29 Laboratory analysis procedures.

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Confirmatory test cutoff  
levels (ng/ml)  
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\* \* \* \* \*  
6-Acetylmorphine \4\..... 10 ng/ml.

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\4\ Test for 6-AM when morphine concentration exceeds 2,000 ng/ml.

Issued this 17th day of November, 1998, at Washington, D.C.  
Rodney E. Slater,  
Secretary.  
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